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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,679	02/10/2004	Assaf Friedler	18396/2282	1897

7590

06/20/2006

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,679

Applicant(s)

FRIEDLER ET AL.

Examiner

Agnes B. Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-27, 29, 39, 40, 44, 45 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-27, 29, 44, 45 and 48-51 is/are rejected.
- 7) ☒ Claim(s) 39 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/06/2006 has been entered.

Claims 1-23, 28, 30-38, 41-43, and 46-47 are cancelled.

This application is a CIP of PCT/GB02/03668 filed on 08/09/2002, which claims foreign priority to the United Kingdom applications 0119557.7 filed on 08/10/2001; 0127917.3 filed on 11/21/2001; and 0210740.7 filed on 05/10/2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 24 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite because it claims "...an isolated peptide which binds to and stabilizes the native conformation of the first polypeptide, in which the peptide comprises a fragment of a second polypeptide, said fragment comprising 600 amino acids or fewer of said second polypeptide..." There are several problems with this claim: 1) a fragment of a second polypeptide is not disclosed and the full structure of the sequence of the polypeptide is also not disclosed, therefore it is impossible to imagine what is the structure of the fragment, where a fragment of a polypeptide could be a single amino acid such as lysine, for example; 2) said fragment is comprising 600 amino

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acids or fewer, therefore once again the fragment could be a single amino acid such as lysine. Therefore, the invention is not specifically disclosed and the claim is indefinite.

Claim 48 is indefinite because it refers to a peptide comprising 200 amino acids or fewer, where the "fewer" can mean one amino acid, as a single lysine? Therefore, a structure of the peptide or its fragment must be specifically disclosed, otherwise the claim is not definite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24 does not satisfy the written description requirement because the structure of a full sequence of the peptide or its fragments is not provided. If the full sequence of the claimed polypeptide is not disclosed then any fragment of the unknown polypeptide cannot be ascertained. The claim states that the fragment is comprising 600 amino acids or fewer, which is meaningless, and thus the sequence structure of the polypeptide must be provided. Further, the written description requirement is not

satisfied because the structure of the fragment (600 amino acids or fewer) does not correspond with its function. Thus, the claim is rejected.

Claim 48 does not satisfy the written description requirement because the fragment of the peptide claimed comprises 200 amino acids or fewer. Further, there is not an adequate description provided concerning any fragments of the peptide claimed, which fragments do not have an assigned sequence structure, and thus there is no disclosure of the fragment claimed (200 amino acids or fewer). Therefore, the written description requirement is not satisfied because the structure of the fragment does not correspond with its function. Therefore, the claim is rejected.

Claim Rejections - 35 USC § 102 (b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-27, 29, 44, 45, and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Naumovski et al., *"The p53-binding Protein 53BP2 Also Interacts with Bcl2 and Impedes Cell Cycle Progression at G2/M,"* Molecular and Cellular Biology, (July 1996), p. 3884-3892.

Naumovski et al. teach the structure of Bcl2-binding protein ("Bbp") that specifically interacts with p53 protein in vivo, where the Bbp necessary requires for its binding to the p53 a specific ankyrin repeats and SH3 domain. See Figure 1, page

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3886, where a fragment of less than 200 amino acids that contains ankyrin repeats and the SH3 domain is depicted in Figure 1 (a). Figure 3, page 3887 shows binding of Bbp protein to p53. (Claims 24, 25, 44, 48).

Figure 6, page 3888, shows an amino acid sequence of Bbp (SEQ ID NO:1), which contains REDEDEIEW amino acid sequence, as part of the SH3 domain necessary for binding of the Bbp protein to p53. The REDEDEIEW amino acid sequence of Bbp protein is identical to the instant invention (Claims 24, 27, 45, 49-51). See Figure 1 and Figure 6, where the fragments of less than 600 or 200 amino acids are known.

Therefore, the claims are anticipated by Naumovski et al. because the REDEDEIEW amino acid fragment of Bbp protein is identical to Claims 27, 45, and 49-51 of the instant invention, and the amino acid fragment has the same function of binding p53 domain.

Claim 26 is included in the rejection because the structure of p53 is known and the mutations R175H, G245S, R248Q, R249S, R273H, R282W, and I195T are well known in the prior art, as pointed out by the Applicant. See specification, page 1, line 21-26, and page 2, line 1-8.

Claim 29 is included in this rejection because the stabilizing molecule is a polypeptide, and therefore it would contain, for example, an amine or amide as its intrinsic characteristic.

Claim Rejections - 35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Winnacker et al. (U.S. 6,451,541, foreign priority, May 14, 1996).

Winnacker et al. teach chaperones Hsp60 that bind to prion protein PrP^C. See column 2, line 20-34. Also, Winnacker et al. teach that prior art chemical chaperones, such as glycerol, trimethylamine N-oxide, and DMSO stabilize PrP^C and prevent its conversion to PrP^{Sc}. See column 3, line 16-24.

Objections to Claims

Claims 39 and 40 are included in the rejection because they depend from rejected independent claim 24.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

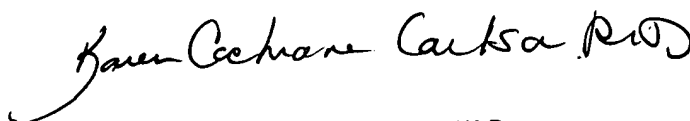
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-273-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER